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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,851	08/09/2006	Karlheinz Bortlik	112701-746	7063

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EXAMINER	
CHEN, CATHERYNE	
ART UNIT	**PAPER NUMBER**
1655	

NOTIFICATION DATE	DELIVERY MODE
10/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/597,851	BORTLIK ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8,9 and 11-26* is/are pending in the application.

4a) Of the above claim(s) *17-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 8-9, 11-16, 22-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 1-4, 8-9, 11-26 are pending. Claims 1-4, 8-9, 11-16, 22-26 are examined on the merits. Claims 5-7, 10 are canceled.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 23, 2008 has been entered.

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-4, 8-9, 11-16, 22-26) in the reply filed on May 9, 2007 is acknowledged.

Claims 17-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 9, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filled, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant us directed to the Guidelines for the Examination of Patent Applications under the 354 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claims are drawn to a method for treating cardiovascular diseases or cancers. However, the specification only discloses a composition of carotenoid-containing material. In analyzing whether the written description requirement is met for the method claims, it is first determined whether a representative number of species have been sufficiently described. In this case, only composition has been described. Applicant has not demonstrated what are the method for treating cardiovascular diseases or cancers. The information is not deemed sufficient to reasonably convey to one skilled in the art that Applicant was in possession of the method of treating cardiovascular diseases or cancers at the time the application was filed. Thus, it is concluded that the written description requirement is not satisfied for the claimed method.

Claims 24, 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and the breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Limited amount of guidance and limited number of working examples in the specification

The Specification does not recite any treatment method for cardiovascular diseases or cancer.

Nature of the invention

There are many types of cardiovascular diseases (see http://www.mayoclinic.com/health/cardiovascular-disease/HB00032) and cancers of which melanoma is untreatable (see http://www.medicinenet.com/script/main/art.asp?articlekey=86977). Thus it would be impossible to treat all types of cardiovascular diseases or cancers.

State of the prior art

There are many causes of cardiovascular diseases or cancers. It has been found that inherited traits that increase susceptibility to cardiovascular disease or cancers; lifestyle factors, such as smoking or alcohol use, can cause cardiovascular diseases or cancers.

Relative skill level of those in the art

Those in the art would have a difficult time to treat cardiovascular diseases or cancers because of the many types of cardiovascular diseases or cancers. Therefore, the relative skill level required would be high.

Predictability or unpredictability in the art

Because of the many types of cardiovascular diseases or cancers, the unpredictability in the art would be high.

The breadth of the claims

The breadth of the claims is broad, particularly for cardiovascular diseases or cancers, in general.

Applicant's claims are broadly drawn to a composition that is able to treat cardiovascular diseases or cancers. In order to be enabled for treatment of a condition, applicant must demonstrate that the invention is able to treat the condition each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to treat cardiovascular diseases or cancers for all potential causes of cardiovascular diseases or cancers. In addition, the art teaches cardiovascular diseases or cancers treatment is not accepted as possible because many risk factors such as

age, race and family history cannot be controlled (see http://www.mayoclinic.com/health/cardiovascular-disease/HB00032; http://www.medicinenet.com/script/main/art.asp?articlekey=86977). Because applicant's specification does not show treatment of cardiovascular diseases or cancers and the art acknowledges that treatment is not currently possible, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually functions as claimed. Therefore, the claims are not considered enabled for the treatment of cardiovascular diseases or cancers.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 8-10, 11-16, 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 1, 15, 22, 24, 26, the term "such that" is indefinite because it does not mean that cis:trans is at 20:80. The term only suggest that is may be cis:trans is at 20:80. Thus, this is indefinite.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 8-9, 11-16, 22-26 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 8-9, 12-16, 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartal et al. (US 5965183) and Chandler et al. (1987, J. Food Sci., 52, 669-672).

Hartal et al. teaches lycopene concentrates for use in food coloring, nutraceuticals, pharmaceuticals, and cosmetic formulations, lycopene from vegetable extracts (column 1, lines 7-9, 16-19), food-compatible liquid, pharmaceutically-acceptable liquid, cosmetically-acceptable liquid (column 6, lines 26-42), oleoresin contains about 2-10% lycopene (Claim 17). Thus at least one carotenoid compound is taught by the reference. However, it does not teach 20:80 cis-trans and the specific carotenoid compounds, improving skin.

Chandler et al. teaches provitamin A carotenoids are plentiful in human foods (Introduction, first paragraph). Cis-trans beta carotene isomers found in fruits and vegetable are 15.7% cis and 75.4% trans in sweet potato; 10.1% cis and 72.8% trans in carrot; 8.8% cis and 80% trans spinach; 16.6% cis and 71.8% trans in collard green; 13.5% cis and 76.7 trans nectarine; 15.4% cis and 76.7% trans in plum (Table 2, page 671).

The method of improving skin is considered to intrinsically teach the claimed method because both the references and the claimed invention are administering the same composition to the same patient. The patient is the same because every person has skin. Thus, on the administration of carotenoids to any patient, an improvement of skin would have had to occur if applicant's invention function as claimed.

Chandler et al. teaches provitamin A carotenoids are plentiful in human foods (Introduction, first paragraph). Hartal et al. teaches lycopene concentrates for use in food coloring, nutraceuticals, pharmaceuticals, and cosmetic formulations, lycopene from vegetable extracts (column 1, lines 7-9, 16-19). Lycopene is a type of carotenoids. Thus, an artisan of ordinary skill would reasonably expect that lycopene could be used as the types carotenoid taught by the references. This reasonable expectation of success would motivate the artisan to use lycopene in the reference composition. Thus, using lycopene is considered an obvious modification of the references.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant for oral consumption. However, the reference

does teach the composition in food and Cis-trans beta carotene isomers are found in fruits and vegetable with 15.7% cis and 75.4% trans in sweet potato; 10.1% cis and 72.8% trans in carrot; 8.8% cis and 80% trans spinach; 16.6% cis and 71.8% trans in collard green; 13.5% cis and 76.7 trans nectarine; 15.4% cis and 76.7% trans in plum (Table 2, page 671). The amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/

Primary Examiner, Art Unit 1655